IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE THIS DOCUMENT RELATES TO BHR-TRACK CASES

MEMORANDUM

Pending before the court is Smith & Nephew's motion for summary judgment as to all claims of plaintiffs in the BHR track with implant dates prior to October 2009 ("Early Implant Plaintiffs"). (ECF 3304, Def.'s Mot.).[1] Plaintiffs responded in opposition (ECF 3477, Pls.' Opp'n), and Smith & Nephew replied in support of its motion (ECF 3515, Def.'s Reply). The court heard oral argument on April 20, 2022. By request of the parties, the court subsequently entered a litigation stay. (*See, e.g.*, ECF 3770, Case Management Order No. 23; ECF 3931, Order Extending Stay). The parties have since requested a ruling on Smith & Nephew's pending motion for summary judgment. For the following reasons, the court will deny Smith & Nephew's motion without prejudice.

I. BACKGROUND

This multidistrict litigation concerns the Birmingham Hip Resurfacing Device ("BHR"), an artificial hip, developed, designed, manufactured, and sold by Smith & Nephew.[2] The BHR replaces the hip joint with metal components—capping the femoral head with a metal covering

[1] ECF citations refer to entries on the Master Docket (1:17-md-02775-CCB) unless otherwise noted.

[2] The court provides only the minimum facts necessary to resolve the pending motion. The court has described the basic facts of this multidistrict ligation in several prior opinions.

and inserting a metal cup within the acetabular cup—to recreate the same ball and socket structure that occurs naturally. The two pieces rub against one another during movement of the patient's hip joint; both are made of cobalt and chromium metal alloys, and the BHR is thus a "metal-on-metal" product.

On May 9, 2006, the FDA granted pre-market approval to Smith & Nephew for the BHR, including femoral head sizes with diameters ranging from 38 mm to 58 mm, for use in both men and women. But research later revealed the friction between the metal components can result in metal debris accumulating in a patient's joints and blood stream. That metal debris can cause pain, metallosis, and other serious complications necessitating corrective surgery or revision to a different device. In 2010, a label change warned of risks for use of the BHR in female patients (generally) and for head sizes 44 mm and smaller in male patients. In 2015, Smith & Nephew voluntarily recalled some BHR devices due to unreasonably high rates of failure in women and in men needing femoral head sizes 46 mm or smaller, for reasons including complications due to metal debris.

Over the following years, hundreds of BHR recipients filed suit and their cases were consolidated into this MDL. The plaintiffs' lead counsel filed a Master Amended Consolidated Complaint to represent the plaintiffs' claims, which alleged that Smith & Nephew committed several common law violations by misrepresenting the safety of the BHR device, failing to supply adverse incident reports to the FDA, and manufacturing a defective product. While the court dismissed some claims as preempted, *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 300 F. Supp. 3d 732, 742–48 (D. Md. 2018) (hereinafter "*In re BHR 12(b)(6) Ruling*"), other claims proceeded to discovery. *Id* at 750 (concluding "the plaintiffs'

failure to warn, negligence and negligence *per se*, breach of express warranty, and negligent misrepresentation claims are fit for discovery").

When, exactly, Smith & Nephew learned of the BHR's risks has been the subject of much debate in this multidistrict litigation ("MDL"). Earlier bellwether cases[3] focused on Smith & Nephew's October 2009 receipt of detailed data about the BHR's performance and elevated revision risk in women and patients with smaller femoral head sizes—the so-called "ad hoc" data from the Australian Orthopedic Association's (AOA's) National Joint Replacement Registry (the "Australian registry"). In those cases, the plaintiffs argued Smith & Nephew—at least upon receipt of the October 2009 data—knew of the dangers associated with the BHR but continued to market the device as superior in safety and effectiveness compared to its competitors. With general liability discovery largely complete, Smith & Nephew now moves for summary judgment as to each claim brought by plaintiffs with implant dates before October 2009.[4]

II. LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) provides that summary judgment should be granted "if the movant shows that there is no *genuine* dispute as to any *material* fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a) (emphases added). "A dispute is genuine if 'a reasonable jury could return a verdict for the nonmoving party.'" *Libertarian Party*

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[3] *See, e.g.*, *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, Civ. No. CCB-17-944, 2021 WL 7186286, at *10 (D. Md. May 17, 2021) [hereinafter "*Redick*"]; *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, Civ. No. CCB-17-3677, 2021 WL 3617419, at *5–6 (D. Md. Aug. 13, 2021) [hereinafter "*Albritton*"] (discussing 2009 ad hoc reports); *see also* ECF 2905, Summ. J. Mem. at 2–3 [hereinafter "*Mosca*"].

[4] *See* ECF 3304-3, Def.'s Ex. A. (listing plaintiffs, as of December 17, 2021, who received BHR implants prior to October 2009). Since this list was prepared, a significant number of these cases have been resolved or otherwise closed. Smith & Nephew provided an updated list of Early Implant Plaintiffs with active cases on April 6, 2023. (*See* ECF 4410, Notice of Am. Ex. A; ECF 4410-1, Am. Ex. A).

of Va. v. Judd, 718 F.3d 308, 313 (4th Cir. 2013) (quoting *Dulaney v. Packaging Corp. of Am.*, 673 F.3d 323, 330 (4th Cir. 2012)). "A fact is material if it 'might affect the outcome of the suit under the governing law.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Accordingly, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment[.]" *Anderson*, 477 U.S. at 247–48. The court must view the evidence in the light most favorable to the nonmoving party, *Tolan v. Cotton*, 572 U.S. 650, 657 (2014) (per curiam), and draw all reasonable inferences in that party's favor, *Scott v. Harris*, 550 U.S. 372, 378 (2007) (citations omitted); *see also Jacobs v. N.C. Admin. Off. of the Cts.*, 780 F.3d 562, 568–69 (4th Cir. 2015). At the same time, the court must "prevent factually unsupported claims and defenses from proceeding to trial." *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 526 (4th Cir. 2003) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778–79 (4th Cir. 1993)).

III. ANALYSIS

Smith & Nephew's motion seeks to capitalize on the plaintiffs' long-standing focus on the company's receipt of Australian ad hoc data in 2009. In several bellwether selections, the plaintiffs identified Smith & Nephew's possession of such data as a defining moment in which the company knew the BHR had a lower success rate than advertised.

The court declines to grant Smith & Nephew's sweeping request for relief. Such a "one-size-fits-all" approach would prematurely resolve numerous claims without the benefit of case-specific discovery. Of course, the parties have completed a substantial amount of discovery on common issues relevant to most cases in this multidistrict litigation. For example, the plaintiffs assert that Smith & Nephew made false representations about the efficacy of its product, so the parties spent time in discovery investigating whether the company had reason to doubt the truth of

its statements. Even assuming the parties have completed enough discovery into these common questions, disputes of material fact bar Smith & Nephew's request for summary judgment at this time.

As the court will explain, the plaintiffs have provided enough evidence for a jury to consider whether—and to what extent—Smith & Nephew knew about the risks of the BHR before October 2009. And because the Early Implant Plaintiffs have not had a fair opportunity for case-specific discovery, the court cannot say at this time whether Smith & Nephew is entitled to summary judgment as to the plaintiffs' claims—each of which require fact-specific, context driven inquiries.

A. Negligent Misrepresentation

A "basic requirement" of a negligent misrepresentation claim is that "the defendant must have provided false information." *Trana Discovery, Inc. v. S. Rsch. Inst.*, 915 F.3d 249, 254 (4th Cir. 2019) (citing Restatement (Second) of Torts § 552(1)) (analyzing North Carolina law).[5] Equally important in establishing a negligent misrepresentation claim is evidence of what the defendant knew, or should have known, when it made the alleged misrepresentation. *See* Dan B. Dobbs et al., *The Law of Torts* § 667 (2d ed.). The court has previously explained that "the duty to make truthful, accurate, and not misleading statements requires only that Smith & Nephew not

[5] Smith & Nephew contends its motion "does not depend upon which underlying State law applies to the Complaints at issue, which involve BHR hip implant patients who had the procedure prior to October 2009." *See* Def.'s Mot. at 13 n.8. Rather, Smith & Nephew asserts no dispute of material fact exists as to the key elements of the plaintiffs' causes of actions. These elements, according to Smith & Nephew are well-established requirements of every jurisdiction at issue. For example, every jurisdiction recognizing the tort of "negligent misrepresentation" would require the plaintiff to show, at some point, that the defendant made a false representation. For simplicity, the court will rely on its prior decisions analyzing the elements of each tort. To the extent applicable state law differs from these general formulations, those distinctions further support the court's hesitation toward granting summary judgment on an MDL-wide basis at this juncture.

create a misleading impression by failing to disclose other *known* information." (ECF 2977, Summ. J. Mem. at 20 [hereinafter "*Sedgwick*"], emphasis added).

Here, summary judgment is inappropriate because a reasonable jury could conclude that Smith & Nephew knew, before October 2009, that the risks associated with its BHR device exceeded those understood by doctors and patients. Moreover, the Early Implant Plaintiffs' need for case-specific discovery precludes the court from awarding Smith & Nephew summary judgment as to other elements of the plaintiffs' claims.

1. Smith & Nephew's Knowledge Before October 2009

Whether Smith & Nephew knew of the BHR's dangers before October 2009 is a genuinely disputed material fact. The court addressed this issue in *Sedgwick*. In that case, the court noted there was "some minimal evidence" indicating Smith & Nephew knew it was overstating the success of the BHR before 2009. *Id.* at 19. The most notable example was Smith & Nephew's realization in 2006 that the company's patient outcome data did not contain every observed revision, thus raising "the inference that the risk of revision of the BHR may have been higher." *Id.* (citing ECF 2757-12, February 2006 Tildesley Email). But that was not enough for Mr. Sedgwick to carry the day. His evidence, at best, simply suggested "Smith & Nephew had a general awareness of the possibility it was overstating the success of the BHR in comparison to its competitors and that it failed to investigate and present those impressions to surgeons." *Id.*

Here, the Early Implant Plaintiffs have a stronger basis for establishing that Smith & Nephew knew of the BHR's higher revision rates before October 2009. To start, the plaintiffs identified reports from the Australian registry in 2004, 2005, and 2006 that disseminated BHR patient-outcome data. (ECF 3477-14, AOA 2006 Annual Report). These reports were not only posted publicly but also sent to Smith & Nephew by Australian registry director Stephen Graves.

(ECF 3615-2, Graves Dep. at 136:14-18).[6] The publications, according to the plaintiffs, exposed the gender difference in resurfacing product revision outcomes. Indeed, the 2006 report revealed the revision rate for resurfacing devices in women was 2.5% at 1 year and 4.2% at 3 years—nearly double the revision rate in men. (2006 AOA Report at 73, Table HT22).

That said, the pre-2009 registry reports did not disaggregate results by company; the data included *all* resurfacing devices. Still, Smith & Nephew's BHR represented a majority of the data points, so the report seemingly provided Smith & Nephew a good indication of its product's performance. (ECF 3477-3, Hungerford Dep. at 94:6–95:1). And Dr. Marc Hungerford, Smith & Nephew's own expert, testified the company likely would have known of these results because the reports were publicly available. (*Id.* at 93:4–17; *see also* Graves Dep. at 173:5–7). Moreover, at least one Smith & Nephew employee even admitted knowing as early as 2008 that women experienced higher revision rates. (ECF 3477-4, Band Dep. at 89:16–24).

Contemporaneous internal communications suggest Smith & Nephew may have known of women's higher revision rates before October 2009. In May 2007, for instance, a Smith & Nephew "Hip Strategy Board Meeting" identified "gender" as a main topic for discussion. (ECF 3477-6, Pls.' Ex. 5, S&N Internal Documents at SN_BHR_MDL_1980717 [ECF Page 30]). And in November 2007, a Smith & Nephew presentation noted the BHR faced "more complications" than expected; that is, the company observed a 2.2% revision rate in just one year. (*Id.* at SN_BHR_MDL_619741 [ECF Page 35], SN_BHR_MDL_619785 [ECF Page 79]). Evidently Smith & Nephew thought one of the "[w]eaknesses" of the BHR, according to the same November 2007 presentation, was that the company's sales representatives lacked "belief in clinical data"

[6] Although Graves testified that he sent Smith & Nephew the reports, he did not confirm the company received those reports. (Graves Dep. at 136:19–137:12).

differentiating the BHR from its competitors. (*Id.* at SN_BHR_MDL_619762 [ECF Page 56]).[7] Above all, Smith & Nephew's employees were not surprised by the higher revision rates for women upon receipt of the October 2009 ad hoc data. After reviewing the ad hoc data, a Smith & Nephew employee noted the Australian registry's analysis "confirm[ed] but quantifie[d] [their] suspicions." (ECF 3477-7, Pls.' Ex. 6, Mogridge Oct. 2009 Email at SN_BHR_MDL_485243).

None of this is to say Smith & Nephew indisputably knew every problem with the BHR in the years before 2009. When and what Smith & Nephew learned about the risks of the BHR remains hotly contested. But a reasonable jury could find that Smith & Nephew learned of those risks before 2009, so summary judgment cannot resolve the "knowledge element" of the plaintiffs' claims.

[7] The plaintiffs identified other documents in seeking to establish Smith & Nephew's knowledge of gender-based metal ion wear in the BHR. For example, the plaintiffs point to a November 2006 internal PowerPoint presentation indicating that Smith & Nephew wanted to reduce metal ion wear in the BHR. (ECF 3477-6, Pls.' Ex. 5, S&N Internal Documents at SN_BHR_MDL_750145 [ECF Page 25]). But the court rejected this argument in *Hand*:

> Hand argues that this [PowerPoint] shows Smith & Nephew knew at the time that metal ion wear was causing a high revision rate in women, but the record does not support this inference. At that time, it was known that metal ion wear was a potential concern (to the point that it was mentioned in the Patient's Guide and the label) but that "there does not appear to be any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects[.]" (ECF 663-2, Ex. B, BHR System Important Medical Information (December 2005) at 14). Hand has no evidence (other than higher revision risk numbers) that the cause was metallosis or that it was known to Smith & Nephew. A desire to reduce metal ion wear is consistent with the simultaneous understandings that metal ions are a potential source of concern and that there is no conclusive evidence about the nature and extent of their detrimental effects.

In re Smith & Nephew Birmingham Hip Resurfacing Hip Implant Prod. Liab. Litig., 603 F. Supp. 3d 222, 237 (D. Md. 2022) (hereinafter "*Hand*").

2. Specific Misrepresentations

While the preceding topic of Smith & Nephew's knowledge presents a common question relevant to every Early Implant Plaintiff, the rest of Smith & Nephew's motion raises issues ill-suited for group-wide resolution absent case-specific discovery.

Take the plaintiffs' negligent misrepresentation claims for example. To prevail on such a claim, a plaintiff must have justifiably relied on a specific false representation. *See Redick*, 2021 WL 7186286 at *10 (applying North Carolina law); *see generally* 26 *Williston on Contracts* § 69:28 (4th ed.) (listing the elements of negligent misrepresentation required by most jurisdictions). Other plaintiffs in this MDL sought to satisfy these elements by arguing that Smith & Nephew made false representations to them or their doctor about the BHR's lower revision rate compared to its competitors.[8] When considering Smith & Nephew's motions for summary judgment in prior cases, the court evaluated *each* representation of the BHR's efficacy made by Smith & Nephew to the plaintiffs and their doctors. After scrutinizing each statement for its truth, the court considered whether the plaintiffs relied on those representations in selecting the BHR over its competitors. Simply put, these types of claims are fact-intensive, patient-specific, and vary widely across cases.[9]

[8] *See, e.g.*, *Redick*, 2021 WL 7186286 at *10 (representations to plaintiff's doctor during training and in marketing materials); *Hand*, 603 F. Supp. 3d at 237–43 (representations to plaintiff via patient guide and representations to plaintiff's doctor during training, component deliveries, email correspondence, and design meetings); *Sedgwick*, ECF 2977 at 15–16 (representations to plaintiff via patient guide and representations to plaintiff's doctor during trainings and in "Dear Doctor" letter); *Albritton*, 2021 WL 3617419 at *5–6 (representations to plaintiff via patient guide).

[9] The factual variations between each plaintiff are sufficient to show the impropriety of Smith & Nephew's one-size-fits-all dispositive motion. But adding to the complexity, still, is the variation in state law applicable to each plaintiff and their claims. For example, the evidentiary threshold for "justifiable reliance" may differ significantly depending on the applicable state law. *See* 26 *Williston on Contracts* § 69:28 (4th ed.) (noting that decisions defining justifiable reliance "have not been harmonious").

Summary judgment, at this time, is inappropriate because the Early Implant Plaintiffs have not yet had an opportunity to conduct case-specific discovery into essential parts of their claims. Generally, summary judgment is inappropriate "where the nonmoving party has not had the opportunity to discover information that is essential to [their] opposition." *Shaw v. Foreman*, 59 F.4th 121, 128 (4th Cir. 2023) (quoting *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th Cir. 2002)). Smith & Nephew argues the plaintiffs' request for case-specific discovery fails to follow the procedural requirements of Rule 56(d). (*See* Def. Reply at 3–7). If a non-moving party shows "by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition," then Rule 56(d)(1) permits the court to defer or deny the motion for summary judgment. *See* Fed. R. Civ. P. 56(d).

Smith & Nephew correctly states that the court must place "great weight" on the affidavit requirement. *See Harrods*, 302 F.3d at 244. That said, the Fourth Circuit has "not always insisted" on a formal affidavit and has excused non-compliance with Rule 56(d) "if the nonmoving party has adequately informed the district court that the motion is premature and that more discovery is necessary." *Id.* Although vague references implying the need for further discovery are insufficient, *Nguyen v. CNA Corp.*, 44 F.3d 234, 242 (4th Cir. 1995), here, the plaintiffs provided several concrete reasons why case-specific discovery is necessary. (*See* ECF 3175, Pls.' Position Statement; *see also* ECF 3477, Pls.' Opp'n at 14–15). That each of the Early Implant Plaintiffs' claims involve "fact-intensive issues" further supports the court's hesitation to grant summary judgment in the absence of case-specific discovery. *See Harrods*, 302 F.3d at 244. And while further discovery may be unnecessary to develop some facts—i.e., whether the individual plaintiffs received and relied on a patient's guide—most of the relevant evidence is not within the plaintiffs' possession. *See Shaw*, 59 F.4th at 129 (noting "premature summary judgment is particularly

disfavored" when critical evidence is in the defendant's possession). It would be quite difficult, for example, for any given Early Implant Plaintiff to know what representations Smith & Nephew made to their doctor in email communications or non-public meetings. *Cf. Hand*, 603 F. Supp. 3d at 242–43 (analyzing email between Smith & Nephew employee and plaintiff's doctor).

Context is key when evaluating whether further discovery is appropriate under Rule 56(d). *See Shaw*, 59 F.4th at 128–29 (identifying certain circumstances and contexts, such as pro se litigation, in which "premature summary judgment is particularly disfavored"). Given the procedural peculiarities of multidistrict litigation, a more lenient approach to Rule 56(d) may be appropriate in some circumstances. Unlike Rule 23(b) class actions, where "questions of law or fact common to class members *predominate* over any questions affecting only individual members," Fed. R. Civ. P. 23(b) (emphasis added), cases in an MDL might share just one common question of fact. *See* 28 U.S.C. § 1407(a) ("When civil actions involving one or more common questions of fact . . ."). To be sure, where groups of cases in an MDL have common legal or factual issues, "a transferee court may dispose of cases in an MDL through summary judgment—and indeed, they often do." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 648 (4th Cir. 2018). "But merits questions that are predicated on the existence or nonexistence of historical facts unique to each Plaintiff . . . generally are not amenable to across-the-board resolution." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268, 302 (3d Cir. 2017), *vacated and remanded on other grounds*, 139 S. Ct. 1668 (2019) (noting that "whether a particular Plaintiff's doctor would have read a warning" was a question of fact that "[e]ach Plaintiff deserved the opportunity to develop"). Indeed, this court rejected a prior attempt by Smith & Nephew to resolve a significant group of cases because, without case-specific discovery, it was "not clear that none of the 175 plaintiffs at issue would be

able to advance a potentially actionable misrepresentation." *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, No. 1:17-2775, 2022 WL 593952, at *2 (D. Md. Feb. 28, 2022) [hereinafter "*Large Femoral Heads Ruling*"].[10]

Ultimately, this court has "broad discretion to determine whether ruling on a particular pretrial motion (such as summary judgment) is appropriate." *In re Lipitor*, 892 F.3d at 648. In considering principles of efficiency[11] and fairness, the court finds the Early Implant Plaintiffs' claims ill-suited for collective resolution. Accordingly, the court will deny Smith & Nephew's motion as to the Early Implant Plaintiffs' negligent misrepresentation claims without prejudice.

B. Remaining Claims

The Early Implant Plaintiffs' remaining claims are similarly unfit for summary judgment without case-specific discovery. Each claim requires a context-driven analysis of (1) specific affirmations or promises made by Smith & Nephew (e.g., breach of express warranty), (2) plaintiff-specific theories of causation (e.g., negligent failure to warn, negligence *per se*, negligent failure to train), or (3) Smith & Nephew's conduct in relation to each plaintiff (e.g., punitive damages). Without case-specific discovery, these types of claims are too fact-specific for adjudication via summary judgment. *See supra* Section III.A.2. Accordingly, the court will deny Smith & Nephew's motion as to the remainder of the plaintiffs' claims without prejudice.

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[10] In that motion for summary judgment, Smith & Nephew challenged the plaintiffs' Rule 56(d) affidavit. Smith & Nephew asserted that plaintiffs' counsel needed to "proffer a specific misrepresentation as to each individual plaintiff without additional discovery, based on their access to their own clients." *Large Femoral Heads Ruling*, 2022 WL 593952 at *3. In rejecting this argument, the court explained that Smith & Nephew's position essentially asked the court to "rule on 175 individual summary judgment motions." *Id.*

[11] Permitting case-specific discovery need not impose a significant time or resource burden on the parties or transferor courts post-remand. Once the plaintiffs have had an adequate opportunity for discovery, Smith & Nephew may renew their motion for summary judgment. The parties will, of course, need to analyze the specific factual context of each plaintiffs' claim.

IV. CONCLUSION

For the reasons stated above, the court will deny Smith & Nephew's motion for summary judgment without prejudice. A separate order follows.

7/13/2023
Date

/s/
Catherine C. Blake
United States District Judge